UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,213	12/22/1998	ERNEST G. SCHUTT	ALLIA.171CPC	3381

21968 7590 04/10/2002

INHALE THERAPEUTIC SYSTEMS, INC
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	30

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 29

Application Number: 09/218,213
Filing Date: 12/22/1998
Appellant(s): SCHUTT et al.

Michael J. Rafa
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 01/17/02.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 2, 6-12, and 39, 43-55 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

6,041,777	FAITHFULL et al.	03-2000
5,855,913	HANES et al.	01-1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 6-12, and 39, 43-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al. US 6,041,777, in view of Hanes et al. US 5,855,913.

Faithfull teaches methods and apparatus of closed-circuit ventilation for pulmonary administration of fluorochemical agent, bioactive agent, and pharmaceutical agent (column 6, lines 19-47). The closed circuit ventilation further comprising a nebulizer in the fluid-conducting reservoir, which may be used to introduce aerosols, mists, sprays or to deliver liquid medium, e.g., fluorochemical to the gas flow path (column 16, lines 27-55). The bioactive agent comprising anti-inflammatories; cardiovascular agent; protein; and antibiotics,

e.g., penicillin, mascolides, quinolines, and tetracycline (columns 25-26). The composition further comprising surfactant (ID).

Although Faithfull teaches the present of surfactant, Faithfull is silent as to the claimed surfactant.

Hanes teaches a pulmonary drug delivery comprising biodegradable particles having density less than about 0.4 g/cm^3, and L-α-phosphatidylcholine dipalmitoyl (DPPC) as a surfactant (columns 4-5). The particles can be suspended in single and double emulsion, phase separation or spray drying (column 6, lines 60-67). The microspheres or particles used in this system can be in different diameter sizes ranging from about 1-1000 μm, and the mean particle size of at least about 5 μm (columns 7-8). Column 9, lines 15-20 further disclose particles having mean aerodynamic diameter size greater than approximately 1 μm. The bioactive agent includes polysaccharides, antibiotics, peptides, or protein in the aerosol form, and to be administered to the respiratory system (column 10, lines 4-60). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Faithfull's surfactant, using DPPC as a surfactant in view of the teaching of Hanes. The reason for this modification is to improve the aerosolization of the particles and to reduce particle agglomeration, thus promote absorption/increase bioavailability of the drug in the lung. The expected result would be a stable dispersion suitable for administration with a nebulizer to deliver drug to the deep lung.

(11) Response to Argument

Appellants argue that Faithfull et al. does not disclose or suggest the use of a fluorochemical as a suspension medium for a respiratory dispersion to be administered via nebulization. Contrary to the Appellants' argument, Faithfull at column 16, lines 40-45, teaches nebulizer is used and can be placed anywhere along the closed-circuit defining the gas flow path to deliver liquid medium, preferably fluorochemical. Accordingly, Faithfull does suggest the use of a fluorochemical as a suspension medium desired by the Appellants.

The Examiner notes that Faithfull at column 17, lines 54-58 states the process is carried out without the preliminary administration of fluorochemical to the lung. However, this is not the closest teaching of Faithfull. As the matter of fact, this is one of the optional embodiment suggested.

The Appellants' arguments regarding to Faithfull does not provide any guidance whatsoever as to respiratory suspensions to be administered via nebulization and is silent as to stability problems associated with suspension for nebulization, are not persuasive. Suspension medium/liquid medium is disclosed in Faithfull at column 6, lines 33 through column 7, lines 1-38, wherein fluorochemical is preferred. Faithfull at column 16, lines 35-38 discloses nebulizer may be used to introduce aerosols, mists, sprays, vapors, powders or combination thereof into the gas flow path thus, maintaining compositional equilibria. Accordingly, it is the position of the Examiner that Faithfull recognizes the advantageous results in the use of nebulizer to provide a stable delivery system.

Appellants argue that Hanes does not teach the use of a fluorochemical as a suspension medium for a respiratory dispersion to be administered via nebulization. In response to Appellants' argument that there is no teaching in both references or no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hanes is relied upon solely for the teachings of L-α-phosphatidylcholine dipalmitoyl as a surfactant, and particles having mean aerodynamic diameter size greater than approximately 1 μm.

Appellants argue that none of the references suggested providing a suspension of perforated micro structures in a suspension medium wherein the volume of suspension medium displaced by the perforated microstructure is less than 70% of the average particle volume of the perforated microstructure as recited in claims 2 and 39. Absent of unexpected result, applicant has not provide any data showing the criticality of "the volume of suspension medium displaced by the perforated microstructure is less than 70% of the average particle volume". No criticality is seen in the claimed volume, since both references recognize the properties desire by the Appellants, e.g., systematic delivery, deep lung incorporation of active agent, stability, and bacteriostatic (see Faithfull, column 6, lines 19-67, column 16, lines 28-

55, column 25, lines 31-67; and Hanes column 6, lines 18-59, column 8, lines 10-29, column 9, lines 43 through column 10, lines 1-57).

Appellants argue that nothing in the art suggested that perforated micro structures suspended in fluorochemical suspension medium results in stable suspensions for nebulization, which resist degradation, flocculation, sedimentation, and creaming in order to provide improved consistency in methods and systems for aerosol administration via nebulization. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., resist degradation, flocculation, sedimentation, and creaming in order to provide improved consistency in methods and systems for aerosol administration via nebulization) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Stability is as discussed above, both Faithfull and Hanes recognize the desirability of obtaining a stable pulmonary delivery system.

For the above reasons, it is believed that the rejections should be sustained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferee

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

Conferee:
James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615